DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services
Center for Substance Abuse Prevention
Center for Substance Abuse Treatment
Rockville MD 20857

January 5, 2007

Dear Colleague:

I am writing to inform you of a significant change in the use of Suboxone and Subutex in the treatment of opioid dependence.

The Office of National Drug Control Policy Reauthorization Act of 2006 (P.L. 109-469, ONDCPRA), has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat. Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time.

Under ONDCPRA (effective December 29, 2006), physicians who meet the following criteria may notify the Secretary of Health and Human Services (HHS) of their need and intent to treat up to 100 patients at any one time: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify their capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

Physicians interested in applying the provisions of ONDCPRA can complete and submit the enclosed form or visit www.buprenorphine.samhsa.gov for instructions on submitting the necessary second notification online. To obtain additional information regarding this matter, contact Nicholas Reuter, Senior Public Health Advisor, at (240)276-2700, or by email at Nicholas.Reuter@samhsa.hhs.gov.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H.
Director
Center for Substance Abuse Treatment

Enclosure:

Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction under 21 USC § 823(g)(2)

Form Approved: 0930-0234
Expiration Date: 03/31/2009
See OMB Statement on Reverse

DATE OF SUBMISSION

Note: Notification is required by § 303(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions on reverse. **For second notifications, you must complete items 6, 8, 9, 10, sign and date the form (item 12).**

1a. NAME OF PRACTITIONER

b. State Medical License Number **c. DEA Registration Number**

2. ADDRESS OF PRIMARY LOCATION (*Include Zip Code*) *(See instruction below)*

3. TELEPHONE NUMBER (*Include Area Code*)

4. FAX NUMBER (*Include Area Code*)

5. EMAIL ADDRESS (*Optional*)

6. PURPOSE OF NOTIFICATION (*See instruction below*)

☐ New Notification ☐New Notification, with the intent to immediately facilitate treatment of an individual (one) patient
☐ Second Notification of need and intent to treat up to 100 patients.

7. CERTIFICATION OF USE OF NARCOTIC DRUGS UNDER THIS NOTIFICATION

☐ **I certify that I will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination.**

8. CERTIFICATION OF QUALIFYING CRITERIA

I certify that I meet at least one of the following criteria and am therefore a qualifying physician (*Check and provide copies of documentation for all that apply*)**:**

☐Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties
☐Addiction certification from the American Society of Addiction Medicine
☐Subspecialty board certification in addiction medicine from the American Osteopathic Association
Completion of not less than eight hours of training for the treatment and management of opioid-dependent patients provided by the following organization(s): Date and location of training
- ☐American Society of Addiction Medicine _____
- ☐American Academy of Addiction Psychiatry _____
- ☐American Medical Association _____
- ☐American Osteopathic Association _____
- ☐American Psychiatric Association _____
- ☐Other (*Specify, include date and location*)_____

☐Participation as an investigator in one or more clinical trials leading to the approval of a Schedule III, IV, or V narcotic drug for maintenance or detoxification treatment
☐State medical licensing board-approved experience or training in the treatment and management of opioid-dependent patients
☐OTHER *(Specify)*_____

☐ **For Second Notification** - I certified qualifications in my initial notification and these qualifications have not changed.

9. CERTIFICATION OF CAPACITY

☐ **I certify that I have the capacity to refer patients for appropriate counseling and other appropriate ancillary services.**

10. CERTIFICATION OF MAXIMUM PATIENT LOAD

☐ I certify that I will not exceed 30 patients for maintenance or detoxification treatment at one time.
☐ Second notification: I need to treat up to 100 patients and I certify that I will not exceed 100 patients for maintenance or detoxification treatment at one time.

11. CONSENT TO RELEASE IDENTIFYING INFORMATION TO SAMHSA BUPRENORPHINE PHYSICIAN LOCATOR WEB SITE (*Read instruction 14 below before answering*)

☐ I consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician Locator Web site.

☐ I do not consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician Locator Web site.

12. I certify that the information presented above is true and correct to the best of my knowledge. I certify that I will notify SAMHSA at the address below if any of the information contained on this form changes. Note: Any false, fictitious, or fraudulent statements or information presented above or misrepresentations relative thereto may violate Federal laws and could subject you to prosecution, and/or monetary penalties, and or denial, revocation, or suspension of DEA registration. (See 18 USC § 1001; 31 USC §§ 3801–3812; 21 USC § 824.)

Signature _____ Date _____

Please send the completed form to:
Substance Abuse and Mental Health Services Administration
Division of Pharmacologic Therapies
Attention: Opioid Treatment Waiver Program
One Choke Cherry Road, Rm 2-1063
Rockville, MD 20857
Fax 240-276-1630
Phone 866-BUP-CSAT (866-287-2728)

This form is intended to facilitate the implementation of the provisions of 21 USC § 823(g)(2). The Secretary of DHHS will use the information provided to determine whether practitioners meet the qualifications for waivers from the separate registration requirements under the Coutrolled Substances Act (21 USC § 823(g)(1)). The Drug Enforcement Administration will assign an identification number to qualifying practitioners and the number will be included in the practitioner's registration under 21 USC § 823(f).

This form may be completed and submitted electronically (including facsimile) to facilitate processing.

1. The practitioner must identify the DEA registration number issued under 21 USC § 823(f) to prescribe substances controlled in Schedules III, IV, or V.	2. Ouly one address should be specified. For the practitioner to dispense the narcotic drugs or combinations to be used under this notification, the primary address listed here must be the same primary address listed in the practitioner's registration under § 823(f).

6. Purpose of notification:

New Notification - an initial notification for a waiver submitted for the purpose of obtaining an identification number from DEA for inclusion in the registration under 21 USC § 823(f).

New Notification, with the intent to immediately facilitate treatment of an individual (one) patient - an initial notification submitted for the purpose described above, with the additional purpose of notifying the Secretary and the Attorney General of the intent to provide immediate opiate addiction treatment for an individual (one) patient pending processing of this waiver notification.

Second Notification – For physicians who submitted a new notification not less than one year ago and intent and need to treat up to 100 patients. (see Office of National Drug Control Policy Reauthorization Act of 2006)

PRIVACY ACT INFORMATION

Authority: Section 303 of the Controlled Substances Act of 1970 (21 USC § 823(g)(2)).
Purpose: To obtain information required to determine whether a practitioner meets the requirements of 21 USC § 823(g)(2).
Routine Uses: Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Medical specialty societies to verify practitioner qualifications.
B. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
D. Persons registered under the Controlled Substance Act (PL 91-513) for the purpose of verifying the registration of customers and practitioners.

Effect: This form was created to facilitate the submission and review of waivers under 21 USC § 823(g)(2). This does not preclude other forms of notification.

Paperwork Reduction Act Statement

Public reporting burden for completing this form is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the completed form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0234. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0234); Room 71-1044, One Choke Cherry Road, Rockville, MD 20857